

Group III: Claims 23-36, drawn to a composition comprising an SMR1 peptide;  
and

Group IV: Claims 37-50, drawn to a method of preparing a medicament.

In addition, the Examiner is requiring election of the one of the disorders and one of the sequences from the following two lists.

Election of a single disorder is required from the following list:

- a) an avoidance disorder;
- b) a decreased awareness disorder;
- c) an autistic disorder;
- d) schizophrenia;
- e) an attention deficit/hyperactivity disorder;
- f) an arousal disorder;
- g) hospitalism;
- h) decreased interest in the environment;
- i) impaired interpersonal functioning;
- j) impaired relationship to the external world;
- k) schizoid personality disorder;
- l) a depressive disorder;
- m) schizophrenia;
- n) a mood disorder;
- o) impaired social activity linked to sexuality;
- p) untimely ejaculation;
- q) hypoactive sexual desire disorder;
- r) simple phobia;
- s) social phobia;

- t) obsessive-compulsive disorder;
- u) acute stress disorder; or
- v) a mental disorder related to a pain disorder.

Election of a single sequence is required from the following list:

- a) SEQ ID NO: 1;
- b) SEQ ID NO: 2;
- c) SEQ ID NO: 3;
- d) SEQ ID NO: 4;
- e) SEQ ID NO: 5;
- f) SEQ ID NO: 6;
- g) SEQ ID NO: 7;
- h) SEQ ID NO: 8;
- i) SEQ ID NO: 9; or
- j) SEQ ID NO: 10.

Applicants have elected, with traverse, Group I, Claims 1-20 and 22 drawn to a method of treating a disease by administering a ligand for examination.

In addition Applicants have elected, with traverse, for search purposes only, the single disorder species (o) impaired social activity linked to sexuality and the single sequence species (b) SEQ ID NO: 2 for examination. Claims 1-20 and 22 read on the elected species.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required. (M.P.E.P. § 803). The burden of proof is on the Examiner to provide reasons and/or examples, to support any conclusion in regard to patentable distinctness (M.P.E.P. § 803). Applicants respectfully traverse the restriction requirement on the grounds that the

Examiner has not carried the burden of providing sufficient reason and/or examples to support any conclusion that the claims of the restricted groups are patentably distinct.

The Examiner states that the methods of Groups I, II and IV are independent and distinct inventions. The Applicants note that Groups I and II are drawn to a method of treating a disease and the peptide administered in Group I is administered together with a second agent in Group II. In addition, all the diseases cited are mental disorders and all groups involve the SMR1-peptide that is to be administered. Therefore, the Examiner's conclusion that the groups are patently distinct is believed to be improper and should be withdrawn.

The Examiner has categorized the relationships between Groups III and IV as process of making and product made. Patentable distinctness may be shown if either or both of the following can be shown: (A) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products, or (B) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). The Examiner states that "... the polypeptide can be prepared or extracted from a variety of sources and can be used in a variety of compositions." However, the Examiner has not provided a sufficient example or reason to support the criteria required under § 806.05(f)). Therefore, the Examiner's reasoning is nearly a restatement of the Examiner's conclusion that the two groups are patentably distinct. As the Examiner has provided no reasons in support of this belief, the Examiner has not met the burden placed upon him, and accordingly, the restriction is believed to be improper and should be withdrawn.

The Examiner has categorized the relationships between Groups I and II and Group III as product and process of use. Patentable distinctness may be shown if either or both of the following can be shown: (1) that the process of using as claimed can be practiced with

another materially different product or (2) that the product as claimed can be used in a materially different process (M.P.E.P. § 806.05(h)). The Examiner states that "... the polypeptide of Group III can be used to generate antibodies as well as used therapeutically." However, the Examiner has not provided a sufficient example or reason to support the criteria required under § 806.05(h). Therefore, the Examiner's reasoning is nearly a restatement of the Examiner's conclusion that the two groups are patentably distinct. As the Examiner has provided no reasons in support of his belief the Examiner has not met the burden placed upon him, and accordingly, the restriction is believed to be improper and should be withdrawn.

The Examiner states that the single disorder species (a)-(v) and single sequence species (a)-(j) are patentably distinct.

Applicants respectfully traverse the Election of Species Requirement on the grounds that the Office has not provided sufficient reasons to support the conclusion of patentable distinctness. Rather, the Office has merely stated the conclusion.

Applicants make no statement regarding the patentable distinctness of the species, but note that for restriction to be proper, there must be a patentable difference between the species as claimed. M.P.E.P. § 808.01(a). The Office has not provided sufficient reasons or examples to support a conclusion that the species are indeed patentably distinct. Accordingly, Applicants respectfully submit that the restriction is improper, and Applicants' election of species is for examination purposes only.

Finally, with respect to the elected species, Applicants respectfully submit that, should the elected species be found allowable, the Office should expand its search to the non-elected species.

Accordingly, and for the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the Election of Species Requirement. Withdrawal of the Election of Species Requirement is respectfully requested.

Further, Applicants respectfully submit that the Office has not shown a serious burden exists in searching the entire application.

Applicants submit this application is now in condition for examination on the merits and early notification of such action is earnestly solicited.

Respectfully submitted,

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